K003437

FEB - 2 2001

510(k) SUMMARY
for
ODYSSEY LX SYSTEM

1. Sponsor

Marconi Medical System, Inc.
595 Miner Rd.
Cleveland, Ohio 44143

Contact Person: Ronald Martone

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Date Prepared: October 30, 2000

2. Device Name

Proprietary Name: Odyssey LX
Common/Usual Name: Computer for Gamma Camera System
Classification Name: System, Tomographic, Computed, Emission

3. Predicate Device

The computer portion of: Prism XPVT (Axis-Irix), K964712, by Marconi Medical Systems, Inc. (was Picker International Inc.)
Cedars QGS/QPS software, K980715, by ADAC Laboratories.
3D-MSPECT, K001026, by University of Michigan.

4. Intended Use

The intended use of the Odyssey LX computer is to be part of a gamma camera system. This could be on a new Axis, Irix, or Meridian system, or as a field upgrade to an existing gamma camera. Gamma cameras are used to do nuclear medicine diagnostic imaging of various body organs. When used with appropriate radio-pharmaceuticals, images are produced representing the internal distribution of radioactivity in the head or body of human patients. There is no difference in intended use between Odyssey LX and the predicate device.

The Odyssey LX device is intended to be used only by trained medical professionals. They are responsible for the choice and administration of radiopharmaceuticals to the patient. Medical professionals also view the images and determine the diagnostic information.

5. Device Description

Hardware Description:

The Odyssey LX computer is part of a gamma camera system. It performs acquisition, processing, display, archiving, and networking functions. The CPU is an Intel Pentium 32 bit processor with a 24-bit display for advanced graphics and visualization.

The Odyssey LX computer will be sold as part of a new gamma camera system, a standalone computer processing station, or as a field retrofit to an existing gamma camera (foreign or Marconi).

Software Description:

The changes to the software include a commercial controlled version of the LINUX operating system. The software includes porting of the previous Odyssey applications software to the new LINUX operating system. This includes the following:

PIXIE is an exclusive Marconi X Window imaging environment for interactive display and analysis.

Frame and curve algebra, count manipulation, image magnification/minification, image mirror, image thresholding, image rotation, image smoothing, image rotation, and histogram modification.

Region of Interest/Curves.

Renal Analysis including Renogram.

Planar Cardiac Analysis.

SPECT / PET Processing.

Quality Control.

There are two new cardiac analysis application software changes. The QPS quantitative myocardial perfusion software from Cedars-Sinai is included. Quantitative Perfusion SPECT (QPS) is a software application designed for the review and quantification of myocardial perfusion SPECT short axis data.

The second cardiac software package is 4D-MSPECT. It is a software application designed to review and quantitatively analyze cardiac SPECT perfusion nuclear medicine studies. 4D-MSPECT operates as an independent application on the Odyssey LX computer system. The application provides tools for viewing standard and gated cardiac SPECT images on both a slice-by-slice basis and as a three-dimensional rendered image

New integrated processing software is being developed to streamline the processing of tomographic SPECT and PET data. This includes the following:

MUGA, Multi-gated analysis for cardiac studies.

Renal analysis.

Auto orientation for cardiac studies.

These applications will be added to those above and will allow the operator to choose from a number of applications for a given type of study.

6. Basis for Substantial Equivalence

The claim of substantial equivalence for the updated computer and software is based upon the same intended use as the predicate device. It performs the same diagnostic studies as the predicate device. The Odyssey applications that existed on the predicate device have been transferred to run on the new hardware and operating system. The new device processes studies at a faster rate and offers optional applications to those present in the predicate device.

Marconi is using the same Cedars QPS software that is supplied to ADAC. This software has been designed to be platform independent.

4D-MSPECT is being supplied to Marconi by the University of Michigan. It is the same software, except for name, as the 3D-MSPECT. It was designed to be platform independent.

The new application software(MUGA, Renal analysis, and Auto orientation) does the same functions as the predicate device applications but offers new quantitative tools and streamlined processing of the presentation to the operator.

The safety of this program has been established through the Marconi software development quality system. This includes software module testing, verification, and validation testing. This process establishes the safety and effectiveness of the Odyssey LX. There are no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Ronald J. Martone
Manager of Regulatory Affairs, Nuclear Medicine
Marconi Medical Systems, Inc.
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K003437
Odyssey LX
Dated: October 30, 2000
Received: November 6, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Martone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) number (if known): K003437

Device Name: Odyssey LX

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	Yes	No	Energy Range (keV)
A. Planar imaging	X		50-550
B. Whole body imaging	X		50-550
C. Tomographic imaging (SPECT) for non Positron emitter	X		50-550
D. Positron imaging by coincidence	X		50-550
E. Positron imaging without coincidence		X	
F. Other indication(s) in the device label, but not included in above list	None		

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003437

Prescription Use ✓ or Over-the-Counter Use _____
(Per 21 CFR 801.109)